REMARKS

The Examiner's presumption that the subject matter of this application has been commonly owned at all relevant times is correct.

The objections to the disclosure have been addressed. The update of the pending application to its issued patent number 6,723,050 on page 8 has been made, and the provisional application 60/430,396 referenced on page 9 has been updated with the serial number and filing date of its corresponding nonprovisional application.

The claims have been amended by deleting the reference numerals to put the claims into the conventional US format. No substantive changes have been made to the claims which would preclude the application of the doctrine of equivalents.

Claims 1-3, 7-8, 11-12, and 15-16 were rejected under 35 U.S.C. §102(b) as being anticipated by US Pat. 6,221,016 (Hayakawa). Claim 1 describes an ultrasonic surgical guidance imaging system which acts to guide the placement or observe the operation of an invasive medical device comprising an ultrasonic probe including an array transducer which steers ultrasonic beams over a volumetric surgical region for image guidance of the placement or operation of an invasive medical device; a transmit beamformer coupled to the array transducer which acts to control the array transducer to transmit a greater beam density in the volumetric region in the vicinity of the invasive medical device; a receive beamformer coupled to the array transducer and responsive to echo signals from array elements for the formation of beams of coherent echo signals; an image processor responsive to the coherent echo signals for producing a three dimensional ultrasonic image of the volumetric surgical region and the invasive medical device; and a display coupled to the image processor which displays the three dimensional ultrasonic image of the volumetric surgical region and the invasive medical device. A constructed embodiment of the invention enables a surgical instrument to be more clearly and readily identified and observed in a 3D ultrasound image by imaging the subvolumetric region of the instrument in the image with a greater beam density.

The Hayakawa patent which, from the claim set, claims five inventions, suggests the 2D imaging technique of scanning the passage area of a puncture needle with a higher scanning density than the surrounding area (invention #1). As explained in column 4, lines 25-49, this technique solves the problem of improving the resolution of the needle passage

without greatly decreasing the frame rate. Hayakawa also suggests using the detected needle tip to set the beam frequency, period, or focal distance (inventions #2-#4). Finally, in the passage beginning at column 32, line 39, Hayakawa discusses 3D imaging of a puncture needle. The problem here is that the path of the puncture needle may turn as it passes through tissue and thereby exit the image plane when imaged by a 2D technique. The solution to this problem, Hayakawa says, is to image the needle path in 3D (invention #5). But Hayakawa notes that it takes a lot of time to generate a 3D image. To solve this further problem, Hayakawa says, it is preferable to restrict the 3D image to a small ROI around the needle tip.

Hayakawa goes on to note that the "various technologies previously explained" (the previously described inventions) are also applicable to the 3D case. But he caveats this guidance with the admonition that they are applicable "as far as they are not in conflict with their nature." The last problem of the 3D case was in fact solved by one of the "previous technologies:" the previously mentioned scheme of a small ROI for enlarged images was used to reduce the time to generate the 3D image and hence maintain an acceptable frame rate.

Nowhere does Hayakawa suggest using the "previous technology" of a higher scanning density around the needle for the 3D case. It is clear from the description of the 3D case that a uniform scanning density is employed. A reading of the claims bears this out. Hayakawa's Claims 1-4 and 11-12 claim the higher scanning density technique (invention #1) with no suggestion of 3D use. Claims 5, 6, and 7 claim the beam frequency, period, and focal distance setting techniques (inventions #2-#4). The claims which do cover the 3D technique, Claims 8-10, do so in combination with the frequency, period, and focal distance setting techniques. It is thus apparent that Hayakawa views these three techniques as applicable to the 3D case and not "in conflict" with the requirements of 3D imaging. He gives every indication that the higher scanning density technique is in conflict with the stated limitation of 3D imaging of its lengthy time required for image generation. If a higher scanning density were employed around the needle in the 3D case, the problem of acquisition time would be made even worse, as an even greater amount of time would be needed to acquire a 3D image with a greater number of scanning beams; the frame rate would become even worse. Thus it is respectfully submitted that a complete reading of Hayakawa shows that the patent does not anticipate

the present invention; rather, it teaches away from the present invention by purposely avoiding the use of a higher scanning density for 3D imaging of a puncture needle and using a uniform scanning approach. For these reasons it is respectfully submitted that Hayakawa does not anticipate Claim 1 or its dependent Claims 2-6. For similar reasons it is respectfully submitted that Hayakawa cannot anticipate method Claims 7-16.

Claims 4-6, 9-10, and 17-20 were rejected under 35 U.S.C. §103(a) as being unpatentable over Hayakawa in view of US Pat. 5,678,552 (Savord). Hayakawa, as previously discussed, does not teach 3D imaging with a greater beam density in the volumetric region in the vicinity of an invasive medical device. Instead, Hayakawa teaches against it. Savord teaches spacing beams more widely at the angular sides of an image rather than at the image center. He does this because the object of interest in his 180° images is usually at the center rather than at the angular sides of the image. This works well if indeed this is true. However, as the drawings in Hayakawa and the present application illustrate, this is generally not the case for an invasive instrument. Hayakawa's drawings show the conventional way of introducing a puncture needle, which is from the side of the probe. Thus, good resolution in the center would not help during introduction of the needle from the side, and it is not possible to move the probe over the insertion point as the needle is being introduced. Furthermore, Savord is only concerned with 2D imaging, not volumetric (3D) imaging and, as Hayakawa makes clear, the two have different considerations involved. Savord is also not concerned with imaging invasive medical devices. For all of these reasons it is respectfully submitted that Hayakawa and Savord cannot be combined to render applicants' volumetric medical device imaging invention of Claims 4-6 and 9-10 unpatentable.

Claim 17 describes an ultrasonic surgical guidance imaging system which acts to guide the placement or observe the operation of an invasive medical device comprising an ultrasonic probe including an array transducer which steers ultrasonic beams over a volumetric surgical region for image guidance of the placement or operation of an invasive medical device; a transmit beamformer coupled to the array transducer which acts to control the spatial beam density of the beams transmitted by the array transducer in the volumetric region; a multiline receive beamformer coupled to the array transducer and responsive to echo signals from array elements for the production of different orders of received multilines in the

vicinity of the invasive medical device and in the volumetric region at locations removed from the invasive medical device location; an image processor responsive to the received multilines for producing a three dimensional ultrasonic image of the volumetric surgical region and the invasive medical device; and a display coupled to the image processor which displays the three dimensional ultrasonic image of the volumetric surgical region and the invasive medical device. By using a different, *e.g.*, higher, order of multiline reception in the vicinity of the invasive medical device, the resolution of and at the work site of the invasive device is improved. Savord is concerned with both multiline reception and scanline synthesis, the latter technique also being referred to as r.f. interpolation. In r.f. interpolation, the values of echoes at different locations are interpolated as a function of their relative locations to calculate an echo value at a new (usually intermediate) location. The present inventors suggest filling in the image volume surrounding the invasive device with synthesized interpolated echoes at page 11, lines 28-29 of the present application, which is r.f. interpolation. They then discuss using different orders of multiline in the middle of page 12. The inventors use the standard definition of multiline, which is the reception of multiple, differently steered receive beams from one transmit beam. See page 12, lines 13-14. Savord only considers using a single order of multiline, which is 2:1 multiline. He makes no suggestion to mix orders of multiline for the same image. See Fig. 18 of Savord which is discussed at columns 11-12. Hayakawa does not appear to be concerned with multiline reception at all. Accordingly it is respectfully submitted that the combination of Hayakawa and Savord cannot render Claim 17 and its dependent Claims 18-20 unpatentable.

Claims 13-14 were rejected under 35 U.S.C. §103(a) as being unpatentable over Hayakawa in view of US Pat. 4,249,539 (Vilkomerson et al.) or US Pat. 5,398,691 (Martin et al.) Claims 13-14 are both ultimately dependent from Claim 11 which recites the step of controlling the beam density of the ultrasonic beams transmitted in a volumetric region to be relatively high in the vicinity of the identified location of an invasive medical device, and to be relatively low at distances of the volumetric region removed from the invasive medical device. As previously mentioned Hayakawa teaches use of a uniform beam density for 3D imaging of a needle and specifically avoids suggesting a higher beam density in the vicinity of a needle when imaging in 3D. Similarly, neither Vilkomerson nor Martin et al. suggest a non-uniform beam

scanning density, either for 2D or 3D imaging. Accordingly it is respectfully submitted that the combination of Hayakawa, Vilkomerson et al. and Martin et al. cannot render Claims 13 and 14 unpatentable.

The patents cited by the Examiner but not applied have been reviewed and are not believed to affect the patentability of the claims above.

The present application was filed only in the United States. Hence, there are no foreign counterpart cases. However there are two companion cases that were based upon the same disclosure and thus have numerous common elements. One of these cases was published along with its search report as WO 2004/084736. The other was published as WO 2004/086082 and was filed in the US as application serial number 10/550,210. In the interest of completeness, copies of the search reports from the two PCT cases are enclosed, as is the Information Disclosure Statement filed in the US application. Copies of the cited references are also enclosed.

In view of the foregoing amendment and remarks, it is respectfully submitted that the informalities of the specification have been resolved, that Claims 1-3, 7-8, 11-12 and 15-16 are not anticipated by Hayakawa, and that Claims 4-6, 9-10, 13-14, and 17-20 are not obvious in view of any combination of Hayakawa, Savord, Vilkomerson, or Martin et al. Accordingly it is respectfully requested that the rejection of Claims 1-3, 7-8, 11-12 and 15-16 under 35 U.S.C. §102(b) and of Claims 4-6, 9-10, 13-14, and 17-20 under 35 U.S.C. §103(a) be withdrawn.

In light of the foregoing amendment and remarks, it is respectfully submitted that this application is now in condition for allowance. Favorable reconsideration is respectfully requested.

Respectfully submitted,

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February 28, 2006